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ship the collected specimen to the drug testing laboratory. The specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely sealed to eliminate the possibility of undetected tampering with the specimen and/or the form. On the tape sealing the shipping container, the collection site person shall sign and enter the date specimens were sealed in the shipping container for shipment. The collection site person shall ensure that the chain of custody documentation is enclosed in each container sealed for shipment to the drug testing laboratory. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site.

(i) *Failure to cooperate.* If the employee refuses to cooperate with the collection process, the collection site person shall inform the employer representative and shall document the non-cooperation on the drug testing custody and control form.

(j) *Employee requiring medical attention.* If the sample is being collected from an employee in need of medical attention (e.g., as part of a post-accident test given in an emergency med-

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ical facility), necessary medical attention shall not be delayed in order to collect the specimen.

(k) *Use of chain of custody form.* A chain of custody form (and a laboratory internal chain of custody document, where applicable), shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the form each time a specimen is handled or transferred and every individual in the chain of custody shall be identified. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site. Every effort shall be made to minimize the number of persons handling specimens.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7355, Feb. 15, 1994; 59 FR 43000, Aug. 19, 1994; 61 FR 37699, July 19, 1996]

§ 40.27 Laboratory personnel.

(a) *Day-to-day management.* (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by a State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), or (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever proce-

dures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the

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procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience, certification or license if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

§ 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory process or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results during storage, and

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continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1)(i) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(ii) Where the employer has used the split sample method, and the laboratory observes that the split specimen is untestable, inadequate, or unavailable for testing, the laboratory shall nevertheless test the primary specimen. The laboratory does not inform the MRO or the employer of the untestability, inadequacy, or unavailability of the split specimen until and unless the primary specimen is a verified positive test and the MRO has informed the laboratory that the employee has requested a test of the split specimen.

(2) In situations where the employer uses the split sample collection method, the laboratory shall log in the split specimen, with the split specimen bottle seal remaining intact. The laboratory shall store this sample securely (see paragraph (c) of this section). If the result of the test of the primary specimen is negative, the laboratory may discard the split specimen. If the result of the test of the primary specimen is positive, the laboratory shall retain the split specimen in frozen storage for 60 days from the date on which the laboratory acquires it (see